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August 16, 2000

BOX PCT

Assistant Commissioner for Patents
Washington, D.C. 20231

PCT/FR99/00253
-filed February 4, 1999

Re: Application of Guy FEUILLOLEY, and Véronique BERNARD
METHOD AND DEVICE FOR STERILIZING HOLLOW BODIES
Our Reference: Q60261

Dear Sir:

The following documents and fees are submitted herewith in connection with the above application for the purpose of entering the National stage under 35 U.S.C. § 371 and in accordance with Chapter II of the Patent Cooperation Treaty:

- ☐ an executed Declaration and Power of Attorney.
- ☑ an English translation of the International Application.
- ☑ 2 sheet(s) of formal drawings.
- ☐ an English translation of Article 19 claim amendments.
- ☑ an English translation of Article 34 amendments (annexes to the IPER).
- ☐ an executed Assignment and PTO 1595 form.
- ☑ a Form PTO-1449 listing the ISR references.
- ☑ a Preliminary Amendment

The Declaration and Power of Attorney and Assignment will be submitted at a later date.

THIS IS THE U.S. NATIONAL STAGE APPLICATION OF PCT/FR99/00253, FILED FEBRUARY 4, 1999.

It is assumed that copies of the International Application, the International Search Report, the International Preliminary Examination Report, and any Articles 19 and 34 amendments as require by § 372(c) will be supplied directly by the International Bureau, but if further copies are needed, the undersigned can easily provide them upon request.

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The Government filing fee is calculated as follows:

Total claims	30	-	20	=	10	x	$18.00	= $180.00
Independent claims	2	-	3	=		x	$78.00	= $.00
Base Fee								$840.00
TOTAL FEE								$1020.00

A check for the statutory filing fee of $1020.00 is attached. You are also directed and authorized to charge or credit any difference or overpayment to said Account. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.492 which may be required during the entire pendency of the application to Deposit Account No. 19-4880. A duplicate copy of this transmittal letter is attached.

Priority is claimed from February 16, 1998, based on French Application No. 98/01937.

Respectfully submitted,

Paul F. Neils
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Date: August 16, 2000

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Guy FEUILLOLEY, et al. 371 of PCT/FR99/00253

Application No.: To be assigned Group Art Unit: To be assigned

Filed: August 16, 2000 Examiner: To be assigned

For: METHOD AND DEVICE FOR STERILIZING HOLLOW BODIES

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to calculation of the government filing fee and examination, kindly amend the above-captioned application as follows:

IN THE CLAIMS:

Claim 3, line 1, change "any one of the preceding claims" to --claim 1--.

Claim 4, line 1, change "any one of the preceding claims" to --claim 1--.

Claim 7, line 1, change "any one of the preceding claims" to --claim 1--.

Claim 11, line 1, change "any one claims 8 or 9" to --claim 8--.

Claim 13, line 1, change "any one of claims 8 to 12" to --claim 8--.

Claim 14, line 1, change "one of claims 1 to 13" to --claim 1--.

Claim 16, line 1, change "one of claims 14 or 15" to --claim 14--.

Claim 20, line 1, change "one of claims 14 to 19" to --claim 14--.

Claim 23, line 1, change "either of claims 21 and 22" to --claim 21--.

Claim 27, line 1, change "one of claims 14 to 26" to --claim 14--.

Claim 29, line 1, change "one of claims 14 to 28" to --claim 14--.

Claim 30, line 2, change "any one of claims 14 to 29" to --claim 14--.

REMARKS

The foregoing amendments are presented to eliminate the multiple dependent claims and thereby avoid the government surcharge, and to ensure the examination of all claims on the merits.

Respectfully submitted,

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534 Rec'd PCT/PTO 16 AUG 2000

METHOD AND DEVICE FOR STERILIZING HOLLOW BODIES

The invention concerns a method for sterilizing hollow bodies. It is most particularly applied, although not exclusively, to sterilizing containers between their fabrication and their filling, or even sterilizing of preforms or blanks of containers at the time of the manufacturing process of sterile containers. It also concerns a device for implementing the method.

Sterilization in the sense of the present invention means any procedure that tends to destroy or reduce elements (microbes, germs, yeasts, etc.) which, if they develop, cause the contents of the hollow body to be inappropriate for the usage or consumption for which it is intended. This term does not necessarily mean a "zero" degree of contamination for one type of element or another, but an acceptable degree as a function of contents, of usage, of its desired shelf life or other parameters. Thus we speak of clean or sterile hollow bodies, depending on the degree of contamination remaining.

Numerous methods have been envisioned to obtain sterile hollow bodies. But they have not been satisfactory for various reasons.

Typically, the basic principle is to inject a sterilizing fluid into the hollow bodies, or on the exterior if there is a need for not only the interior but also the exterior to be sterile.

It is this fluid that is used and the operating method applied which determines the degree of sterilizing achieved.

Known processes consist in immersing the hollow bodies or in filling them with a sterilizing liquid. These methods require draining, then drying of the hollow bodies,

on one hand; they involve a great consumption of fluid, on one hand, or even require recycling of significant volumes of the sterilizing liquid, on the other.

Draining, as well as drying, when the body has been completely filled, are delicate operations; it is important that these operations not become the cause of new contamination.

On the other hand, the recycling of the liquid, if consumption reduction is desired, requires a complex installation.

Other methods consist in the use of sterilizing gases. The installations for this application are complex and have a high consumption. Thus, for example, there have been conceptions of manufacturing the sterile containers of plastic materials, such as bottles, by insufflating them with sterile air or air with the addition of sterilizing agents. Obtaining sterile air is an operation that requires methods that become more massive, the greater the volume necessary for insulation. In fact, it should be remembered that to manufacture bottles of plastic material by using the injection-insulation technique, insulation pressures are on the order of 40 bars, which means that the fabrication of a one-liter bottle involves the use of 40 liters of air. In addition, after insulation, it is necessary to de-gas the containers. Depending on the nature of the sterilizing agent used, it may be impossible to conceive of releasing it into the atmosphere, which again entails the necessity of a complex recycling installation.

Methods have thus been conceived which consist of atomizing a liquid sterilizing agent (such as hydrogen peroxide, peracetic acid or other) and applying it in the form of droplets on the surfaces to be sterilized of the packaging material.

The methods of this type and the corresponding devices known to date are not fitting in that they do not

make it possible to ensure a distribution of the sterilizing agent over all of the internal surface, also called the interior wall, of the hollow body when it is essentially this surface which must be sterilized; in addition, the known devices are not "universal" in the sense that they do not make possible the processing of hollow bodies having shapes that are different from each other or even that they are not suitable for processing of every type of material.

Thus, for example, the device described in US patent no. US 4 631 173 does not make it possible to ensure a homogeneous distribution of the agent since it uses a heated surface on which the sterilizing agent is projected with force. In contact with this surface, the agent vaporizes, on one hand, and is sent toward the surfaces to be sterilized. It is necessary to aim the heated surface so that the agent can be dispersed in the hollow body.

Thus, it is necessary to adapt the configuration and the orientation of the heated surface to the volume and to the shape of the hollow bodies. If the hollow body is very deep, it is not certain that the sterilizing agent will be sent toward the surfaces that are furthest away.

This device is not appropriate for sterilizing bottles or preforms (or blanks) of bottles since their opening is not large enough so that the dispersed product may be directed to the interior of this type of hollow body except if it has a heating surface of very small dimensions so that it can be introduced into the opening of the container. But in this case, it would be difficult to bring the sterilizing agent in contact even with this surface. In addition, the heat energy necessary for vaporizing would be likely to deteriorate the hollow body (bottle or preform) when it is made of a thermosensitive material.

The procedure described in the German patent request 43 05 478 does not make it possible to ensure homogeneous distribution of the sterilizing agent and is not appropriate for every type of material making up the hollow bodies.

It does not make it possible to ensure homogeneous distribution of the sterilizing agent since the latter is injected by means of a nozzle which opens out toward the base of the hollow body. The agent is introduced into the nozzle in a mixture with water vapor in order to, in theory, go into the vapor phase in the hollow body. However, if the tube cools, the water vapor-sterilizing agent condenses, and then the drops fall to the base of the body instead of the vapor mist. Because of this, there is a risk of accumulation of drops on the base and not an ascent of the agent on the walls.

In order to reduce the risk of accumulation and/or prevent condensation of the agent at the bottom of the container, it is provided that the hollow bodies will be reheated, which makes it possible to reactivate the vaporizing of the agent.

This does not in any way ensure that the vaporized agent will distribute itself properly over all the walls of the hollow body.

In addition, this reheating method makes this operation impossible with certain types of materials, particularly thermosensitive materials (plastics) or insulating materials. In fact, a hollow body of thermosensitive material has the risk of being deteriorated by the method (risk of deformation by retraction of the material in particular); an insulating material considerably increases the processing temperature since the supply of heat by reheating the hollow body is carried out on the exterior; at the limit, it will become impossible to implement the method as the necessary heating time becomes greater.

This method again makes it necessary to modify, in particular, the installation (change in the reheating chamber) in

the case of changing the shapes or the sizes of the hollow bodies to be sterilized.

Another disadvantage of this method is that a lack or an absence of sterilizing agent in case of failure of a control system will not be detected since the agent is normally mixed with water vapor. In the case of injection of water vapor alone, the absence of a sterilizing agent cannot be easily detected by an external observer.

Other approaches have been taken which consist in particular of propelling the sterilizing agent in the hollow body using a compressed gas.

This solution does not make possible the assurance of a proper distribution of the agent since at the time of its introduction under pressure it creates compression knots and nodes, turbulent phenomena, or other obstacles to the said distribution.

Thus, the object of the invention is a method and a device that does not present one or the other of the disadvantages mentioned above, i.e. which makes possible: a distribution over all of the surface of the sterilizing agent; a possibility of application without significant modification of the device in the case where the hollow bodies to be sterilized are changed; an application to all types of hollow bodies (bottles, pots, flasks, troughs, tubes, etc.); an application to any type of material; easy detection of an absence of sterilizing agent.

According to the invention, a method for sterilizing hollow bodies, particularly of containers or preforms of containers, by prior application of a sterilizing agent on the surfaces to be sterilized, is characterized in that it consists of causing a gaseous current that moves the vaporized agent toward all of the surfaces to be sterilized in order to distribute it on all of the said surfaces.

Thus, by moving, i.e., by guiding, the agent onto the surfaces, a proper distribution is obtained, in contrast to the devices where the agent is projected or insufflated into the interior. A simple guiding of the agent after it has been vaporized makes the procedure useful with any type of material since, in particular, there is no need to heat the hollow bodies; as will be explained below, the method may be used with a relatively simple device that can be used for any type of hollow bodies no matter what their shape or dimension and without there being a need to modify them, in particular in shape and/or dimensions of the bodies; finally, the absence of agent is easily detectable; it is adequate simply to confirm the arrival of the agent at the moment of vaporizing.

Another advantage is that the guiding of the agent by a gaseous guiding current makes it possible to carry out the sterilizing no matter what the position of the hollow bodies, i.e. no matter what the position of their openings (top, bottom or other).

According to another characteristic, the agent is vaporized on the outside of the hollow bodies close to its opening, and the guiding current is implemented by causing an aspiration of the vaporized sterilizing agent using an aspirating means acting opposite the opening of the hollow body.

According to another characteristic, in an installation for implementation intended for sterilizing tubes that are open at their two ends, the aspiration is caused using a device acting across from the end of the tube opposite to that in the area of which the vaporizing is carried out.

According to another characteristic of the method according to the invention, the phases of vaporizing and introduction of the agent into the hollow body are preceded by a phase of withdrawing particles or non-adhering elements that are present in the

hollow body, such as dust introduced during storage.

According to another characteristic, the vaporizing phase is followed, after a period of contact, by a phase of withdrawal (drying) of the remaining sterilizing agent.

Other characteristics and advantages of the invention will become apparent from reading the description that follows given with regard to the figures attached, in which:

- Figure 1 is a schematic diagram of a device for sterilizing hollow bodies conforming to the invention;

- Figure 2 is a schematic diagram of a device for withdrawing the sterilizing agent after a determined contact time;

- Figure 3 is a schematic view from above of a variation of a device according to the invention;

- Figure 4 is a schematic view of a device used for withdrawal of the sterilizing agent;

- Figure 5 is a block diagram of an installation using the invention;

- Figure 6 is a diagram of a variation of the devices in Figures 1 to 4.

The device shown in Figure 1 comprises an injector or atomizer 1 for the sterilizing agent that can be vaporized such as hydrogen peroxide, peracetic acid or any other suitable agent. The injector is connected on one hand to a reservoir for the agent, not shown, and to control means for its opening and closing on the other hand.

The injector may be mechanical, electromechanical, pneumatic or from any other appropriate type.

The output of the sterilizing liquid from the injector is directed toward an evaporator 2 enclosed in housing 3, cylindrical in the example illustrated. An opening 4 is arranged in the cylindrical wall of the housing across from the injector output in order to permit atomizing of the liquid on the evaporator 2.

In the embodiment shown, the evaporator 2 is made up of a cylinder of a material that is a good thermal conductor and provided on its periphery with blades 5 in the form of annular protuberances. Preferably, the blades are distributed evenly over the height of the cylinder making up the evaporator body.

The external diameter of the evaporator is less than the interior diameter of the housing 3 so that after evaporation, the sterilizing agent may circulate, as will be explained below.

Housing 3 is closed, on its upper end in the picture, by a cover 6 with an opening at its center for the passage of a hollow tube 7.

Preferably, as shown in the figure, the tube 7 passes across an axial orifice, not referenced, of evaporator 2.

The lower end of the housing is intended to be located across from the opening 8 of the hollow body 9 (in this case a container such as a bottle) to be sterilized. It is open and, preferably, the shape and the interior dimensions of the opening of the end correspond to that of the interior opening of the hollow body.

The evaporator 2 is held in place in the housing 3 using fastening means 10 such as screws or spacer sleeves arranged close to the end of the evaporator that is furthest away from the hollow body 9 in order not to

interfere with the trajectory of the agent between the evaporator 2 and the hollow body 9.

The reheating means 11 of the evaporator 2 are provided to bring it to a temperature that makes possible semi-instantaneous evaporation of the sterilizing agent when it arrives in contact. In the example shown, these means 11 are made up of a heating resistor arranged in the thickness of the wall of the housing 3 in such a way as to reheat the latter and to reheat the evaporator 2 by thermal conduction across the material that makes up housing 3 and evaporator 2 and/or by confection in the free space between the interior wall of the housing 3 and evaporator 2.

Preferably, at least the tube 7 can be slid (double arrow 12) to facilitate placement of the hollow body with respect to the device. Thus, the hollow body 9 may be placed across from the device by simple lateral translation by moving the tube away from the trajectory of the hollow body. It is thus possible to use transfer systems known in and of themselves to ensure the placement of the hollow bodies such as transfer gripper mechanisms mounted on articulated arms or even transfer mechanisms with wheels or plates having notches or sockets for guiding the hollow bodies.

Alternatively, it could be conceived that the placement of the hollow body is carried out by subjecting it to an axial translation, tube 7 remaining fixed.

In one embodiment, only the tube 7 slides. Thus, it slides relative to the hollow body and the assembly made up by the evaporator 2 and the housing 3 at the time of the placement or withdrawal of the hollow body.

In one variation, it is the tube 7 and the assembly consisting of evaporator 2, housing 3 which are translated axially at the time of placement or withdrawal of the hollow body 9.

The end of the tube 7 located on the side of the cover 6 of housing 3 is connected to an aspiration source 13. When the hollow body 9 is in place, as is shown in figure 1, the end of the tube opening out into the hollow body 9 is close to the base 14 of it.

The device function is as follows.

Evaporator 2 is heated by heating means 11 in such a way that its temperature would be adequate to cause immediate evaporation of the sterilizing agent when the latter projected by the injector 1 arrives at its contact.

By way of example, when the agent is hydrogen peroxide, the evaporator 2 is brought to a temperature between 100°C and 400°C, preferably on the order of 150 to 200°C.

The opening 8 of the hollow body 9 is placed across from the opening of the housing without ever coming into contact with it so that an air current can be created between the orifice 4 of the housing 3 and the gap that exists between the container and the housing.

In addition, the fact that a distance is maintained between the housing and the hollow body prevents deterioration of the latter when it is made of a thermosensitive material.

Tests have given evidence that a distance between 0.1 mm and 5 mm will obtain good results and that the best results would be obtained by allowing a distance between 0.5 and 3 mm to exist.

Preferably, the device is maintained in a sterile air environment in a housing to prevent additional dust particles from penetrating into the hollow bodies to be sterilized. For this, known means are used such as an isolation chamber with laminar sterile air flow in which the device is installed.

After the device and the hollow body 9 have been placed in the correct position relative to each other, the sterilizing agent is atomized or injected by the injector or atomizer 1 on the evaporator 2 across the orifice 4 arranged in the housing 3. The high temperature of the evaporator 2 causes immediate vaporizing of the sterilizing agent and the aspiration promoted by means 13 across the tube 7 opening near the base 14 of the hollow body 9 creates a guiding current in the air contained in the hollow body along with a guiding of the vapors of the sterilizing agent, which are thus directed to the interior of the hollow body 9 and are deposited on the internal surface of the hollow body. This current is indicated schematically by arrows 15 on the figure.

In addition, given that the hollow body is at ambient temperature, the sterilizing agent condenses when contacting the internal surface of the hollow body.

After a specified period of contact, the sterilizing agent contained in the hollow body is withdrawn.

Tests carried out on preforms of containers of plastic material (PET) or on the containers themselves show that a period of contact between 2 and 6 seconds makes it possible to obtain a degree of asepsis compatible with standards for foodstuffs in force, by using hydrogen peroxide concentrated to 35% as the sterilizing agent.

Aspiration across tube 7 may be continuous or sequential. If it is sequential, it is important that it starts at the latest at the moment of injection in order that all of the sterilizing agent injected and vaporized will be aspirated toward the hollow body. One consequence of aspiration starting with a slight delay from the injection would be the risk of loss of a certain quantity of agent by evaporation toward the outside, notably by way of orifice 4. This risk of loss does not exist any longer if the aspiration starts at the moment of injection.

In addition, whenever it is sequential, it must be continued at least until all of the surface to be treated is covered with sterilizing agent.

At the end of the contact period mentioned above, the hollow body is sterile. However, it is necessary to withdraw the sterilizing agent, for example by drying the hollow body if the agent is liquid.

In order to do this, it is possible to insufflate a sterile gas such as dry or hot sterile air in the hollow body, i.e. preferably to drive the hot air to the inside of the hollow body by aspiration. In fact, insulation with hot air is difficult in the case of hollow bodies having a specific geometry, for example in the case of bottles where the flow of air is preferentially directed toward the bottom but does not come in contact with all of the walls.

In addition, an advantage of the solution consisting of guiding hot air is that it is possible to use the same device as that employed for vaporizing and deposit of sterilizing agent by substituting for injector 1 a heat generator 16 such as is shown in Figure 2.

In the case of the use of hot air, the heat generator 16 may be a hot air nozzle at high temperature or a burner. The heat or the flame is directed toward the orifice 4 and simultaneously an aspiration is created in the hollow body (in this case, a preform of a container) to channel the flame due to the heat toward the walls.

Use of a flame or of a hot air generator is not contraindicated for drying hollow bodies of thermosensitive material such as containers or preforms of containers of thermoplastic material.

In fact, the time of exposure to the heat is very short. Taking into account the thermal inertia of the material,

the guided hot air simply has the function of sweeping or drying the hollow body.

Still, when the hollow body to be sterilized is of thermoplastic material, it is preferable to provide means for preventing a direct transfer between the output of the generator 16 and the exterior of the hollow body 9.

These means may be made up by a plate 17 for protection of the opening of the hollow body encircling at least partially the housing 3 and arranged between the orifice 4 of the hot air passage of the flame and the opening of the housing 3 on the side of the hollow body 9, as is visible in Figure 2.

Alternatively, a hood could be provided that largely covers the opening of the hollow body.

In Figure 3, there is a schematic illustration in cross section view from above at the level of the orifice 4, of a possible arrangement of a single device serving simultaneously for depositing the sterilizing agent and for drying.

Simultaneously, the outputs of an injector 1 and that of a hot air generator 16 are directed toward the orifice 4 of the housing 3. In this case, it is necessary that the generator 16 of hot air be of the sequential type so that the heat (flame or hot air) will not be applied during the injection/vaporizing/contact of the sterilizing agent phases.

Preferably, the drying phase for the hollow body is carried out in two steps: a first step in which heat (flame or hot air) is applied in the housing, the aspiration being active; and a second in which the aspiration continues while the heat is no longer applied in such a way that all of the vapor residues will be evacuated.

By way of example, it would be possible to dry the preforms of containers of thermoplastic material by applying a

flame for 1 to 3 seconds at the orifice 4 and by continuing aspiration between 2 and 6 seconds.

Figure 4 represents a schematic cross section of a device provided specifically for drying the hollow bodies.

The main difference from the device in figures 1 to 3 is that it no longer includes the evaporator.

It comprises a housing 18 in the form of a cylindrical tube 19 closed at one of the ends and open at the other. The housing has an orifice 20 across from which a heat generator 21 is located, a burner for example.

A cross rod 22 crosses the housing in such a way that one 23 of its ends is located close to the base of the hollow body 24. The other end of the rod is connected to an aspiration device 25.

When the heat, in this case a flame 26, is applied at the same time as the aspiration, a flow is created (arrows 27) aspirating the flame and the vapors of the sterilizing agent and drying the interior surface of the hollow body.

Preferably, the phase of injection/vaporizing of the agent is preceded by a phase of withdrawing, from the hollow body, of particles such as dust or other elements that do not adhere.

This phase may be carried out by aspiration and/or insulation or any other appropriate method.

In one embodiment, a device similar to that used for withdrawing traces of the sterilizing agent and shown in Figure 4 is used with the difference that the device does not contain a hot air generator. Thus, the device comprises the means of aspiration 22, 23, 25 and a housing 18.

In a variation, instead of aspiration by the rod 22, the phase of withdrawal prior to the injection of the agent is no longer carried out by aspirating using the rod 22, but by aspirating using the housing 18 by way, for example, of the orifice 20. In this case, the rod 22 makes it possible to supply the air compensating the vacuum created at the time of aspiration.

In one embodiment, all of the phases mentioned above are carried out with one and the same device, such as the one shown in Figure 3, and thus comprising an evaporator, means of aspiration, means of injecting the agent and a hot air generator, i.e., all of the means shown in more detail in Figures 1, 2 and 4.

However, for reasons of efficiency of the various processes to be carried out, it is advantageous to implement at least the preliminary phase of dust removal in a separate device from the one or the ones used for the later phases of sterilizing, i.e., injection/vaporizing/contact and drying.

In fact, the first phase consists of recovering the dust or other particles while in the time afterward, this includes the gas or vapors that are aspirated. The dust or other particles must be recovered and disposed of while the gas or vapors of sterilizing agent may be recycled. Thus, if it is desirable to arrange gas vapor recycling, it is necessary to have separate means of aspiration and it is desirable to differentiate the respective devices.

In addition, the use of a single device is not suitable when the device must have higher rates of speed, for example, when the hollow bodies to be sterilized are preforms of containers (bottles or others) of plastic material brought in succession, in line, to the intake of a machine for blow molding containers or containers at the end of fabrication.

In such a case, it is desirable and preferable to separate all of the phases and to implement them by moving the hollow bodies along a line to the separate phases, making in-line processing possible.

Figure 5 illustrates the schematic diagram of an installation that makes it possible to carry out all of the phases mentioned above at the time of processing preforms 28 for sterilizing them upstream of a machine 29 of blow molding/filling of containers 30.

The preforms 28, arriving continuously in line in the direction of arrows 31, are successively brought into a stage 32 of withdrawal (dust removal or other). This step comprises the means, not shown, for processing several preforms.

Then, the preforms are transferred to a step 33 carried out by injection, vaporizing and contact of a sterilizing agent. This step comprises one or more devices conforming to those in Figure 1.

Then the preforms are transferred to a step 34 of drying. It should be noted that the time of transfer between the preceding state and the latter state can be well used for prolonging the time of contact necessary for sterilizing.

Then, the preforms are transferred to the machine 29 for fabrication/filling of the containers.

Preferably, the machine 29 and the various steps of processing 32, 33, 34 are enclosed in a sterile enclosure with laminar flow.

This enclosure is shown schematically by the broken line 35 in Figure 5.

Each of these processing steps, 32, 33, 34 respectively, may comprise at least one appropriate fixed device

to which the hollow bodies are brought step by step for their processing.

However, this structure is not well adapted to high rates of processing speed required in a number of installations; it is for this reason that preferably each step is carried out in order to permit in-line processing of the hollow bodies.

In one embodiment, each step comprises the means to hold or support the hollow body associated with the means for continuous transport. It is thus possible to process the hollow bodies gradually as they arrive in the installation. The rate of processing is a function of the dimensions of each of the stages and thus of the number of devices that each includes.

The rate of processing is a function of the size of each of the stages and thus of the number of devices incorporated in each.

In one variation that is not shown, the sterilizing phases are carried out after fabrication of the containers, for example, before they are filled. Various steps, notably that 33 for sterilizing itself, are then downstream of the output of machine 29. In this case, machine 29 must not be in the laminar flow of sterile air; but it is important that at least the steps 33, 34 of sterilizing and drying would themselves be under laminar flow.

Figure 6 shows a schematic diagram of the invention when it is used for sterilization of hollow bodies that are open at two of their ends. This is the case, e.g. with tubes or various conduits.

In this case, the aspiration is not carried using a tube crossing the housing 36 and opening out at the end 37 of the hollow body 38 opposite to the one 39 close to which the housing 36 is located with the injection means (not shown) and/or the means for generating hot air (not shown); rather, it is implemented using

a tube 40 located at the open end 37 of the hollow body opposite the one 39 where the housing is located. The tube 40 is connected to aspirating means 41.

Naturally, the invention is not limited only to the embodiments described. It encompasses all the possible equivalent and varied embodiments.

CLAIMS

1 - Method for sterilizing hollow bodies (9) having an opening (8), of a consistent type to deposit on the surfaces to be sterilized a sterilizing agent that is previously vaporized, characterized in that it consists of carrying out the vaporizing of the agent outside the hollow body, close to its opening and with the use of a means of aspiration opening out into the hollow body opposite the said opening, to cause a gaseous current for guiding the vaporized agent toward all of the surfaces to be sterilized in order to distribute the agent on all of the said surfaces.

2 - Method for sterilizing hollow bodies (38) having two openings, of a consistent type for depositing on the surfaces to be sterilized a sterilizing agent that is previously vaporized, characterized in that it consists of implementing the vaporizing of the agent outside the hollow body, close to one of its openings and with the use of a means of aspiration opening out into the hollow body opposite the said opening, to cause a gaseous current for guiding the vaporized agent toward all of the surfaces to be sterilized in order to distribute the agent on all of the said surfaces.

3 - Method according to any one of the preceding claims, characterized in that the sterilizing agent is chosen from among the agents available in liquid phase, such as hydrogen peroxide, peracetic acid or other.

4 - Method according to any one of the preceding claims, characterized in that the phases of vaporizing and introduction of the agent into the hollow body are preceded by a phase of suppression of particles or other non-adherent elements present in the hollow body.

5 - Method according to claim 4, characterized in that the suppression phase is carried out by insulation.

6 - Method according to claim 4, characterized in that the suppression phase is carried out by aspiration.

7 - Method according to any one of the preceding claims, characterized in that the vaporizing phase is followed, after a period of contact by the agent with the surfaces to be sterilized, by a phase of withdrawal of the remaining sterilizing agent.

8 - Method according to claim 7, characterized in that the withdrawal phase is carried out by injection of a withdrawal agent in the inside of the hollow body.

9 - Method according to claim 8, characterized in that the withdrawal agent is a sterile dry or hot gas.

10 - Method according to claim 9, characterized in that the withdrawal agent is brought by aspiration into the inside of the hollow body, by using aspiration means acting in the hollow body opposite its opening.

11 - Method according to any one claims 8 or 9, characterized in that the sterile gas is hot air injected using a hot air nozzle.

12 - Method according to claim 8, characterized in that the withdrawal phase is carried out with the use of a flame injected by a burner and brought by aspiration into the inside of the hollow body with the use of the aspiration means acting in the latter opposite its opening.

13 - Method according to any one of claims 8 to 12, characterized in that the withdrawal agent, dray or hot gas or flame respectively, is injected on the outside of the hollow body close to its opening.

14 - Device for carrying out the method according to one of claims 1 to 13, characterized in that it comprises the means (1) for injection of a vaporizable sterilizing agent, and evaporator (2) across from the output of the injection means, aspiration means (7, 13; 40, 41)

opening out into the hollow body in such a way as to act inside same to cause a gaseous current guiding the vaporized agent toward the interior surfaces of a hollow body (9; 38) when the later is in place with respect to the device.

15 - Device according to claim 14, characterized in that the evaporator is enclosed in a housing (3; 36) arranged on the outside of the hollow body (9; 38) close to the opening of the latter and provided with an opening (4) across from the output of the means (1) of injection, of an open end having the shape and interior dimensions essentially corresponding to those of the interior opening of the hollow body (9; 38).

16 - Device according to one of claims 14 or 15, characterized in that the means (7, 13; 40, 40) for causing the gaseous current are made up of a tube (7; 40) connected to an aspiration source (13; 41).

17 - Device according to claim 16, characterized in that since the hollow body is in the shape of a container, i.e. open at one of its ends and closed at the other, the tube (7) is introduced through the opening of the hollow body; the tube has an end opening out next to the base of the hollow body and its second end, located at the side of the housing (3) is connected to the aspiration source (13).

18 - Device according to claim 17, characterized in that the tube (7) crosses the evaporator (2) and the housing (3).

19 - Device according to claim 16, characterized in that since the hollow body (38) is a tube or a conduit open at two opposite ends, the aspiration is carried out by arranging the aspiration tube (40) at the end of the hollow body opposite the one where the injection takes place.

20 - Device according to one of claims 14 to 19, characterized in that it comprises the means for withdrawing the sterilizing agent after a period of contact in the hollow body.

21 - Device according to claim 20, characterized in that the means have a generator (16; 21) for dry or hot sterile air.

22 - Device according to claim 21, characterized in that the generator is a burner (21).

23 - Device according to either of claims 21 and 22, characterized in that the generator (16;21) is placed outside the hollow body near its opening, and it has means to direct the heat inside the hollow body.

24 - Device according to claim 23, characterized in that the means to direct the heat are made up of an aspiration tube (7; 22; 40) of which the aspiration end opens out into the hollow body in a zone that is at a distance from its opening in order to direct the heat into all of the hollow body.

25 - Device according to claim 24, characterized in that since the hollow body is a container, the tube (7; 22) penetrates through the opening of the latter and opens out close to its base.

26 - Device according to claim 24, characterized in that since the hollow body is a tube or a conduit, the tube (4) is arranged at the end of the hollow body opposite to that close to which the heat generator (16; 21) is located.

27 - Device according to one of claims 14 to 26, characterized in that it comprises the means for carrying out a suppression of dust or other particles previous to the vaporizing phase and the placement of the sterilizing agent.

28 - Device according to claim 27, characterized in that the suppression is carried out by aspiration and/or insulation.

29 - Device according to one of claims 14 to 28, characterized in that it is surrounded by a laminar flow (35) of sterile gas, in excess pressure, such as air.

30 - Installation for manufacturing and/or filling containers, characterized in that it comprises a device according to any one of claims 14 to 29.

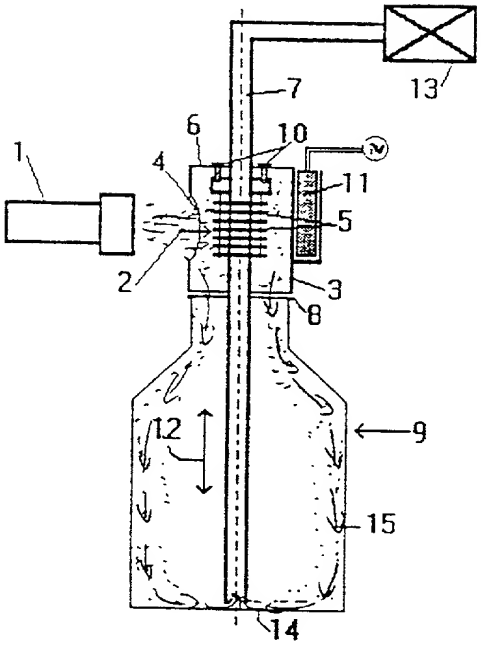

Fig. 1

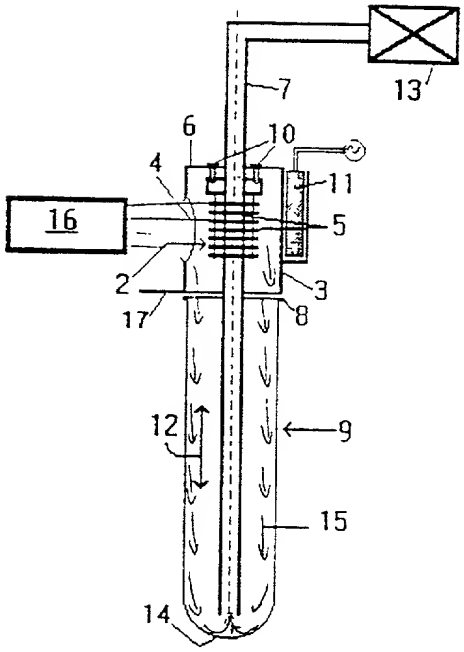

Fig. 2

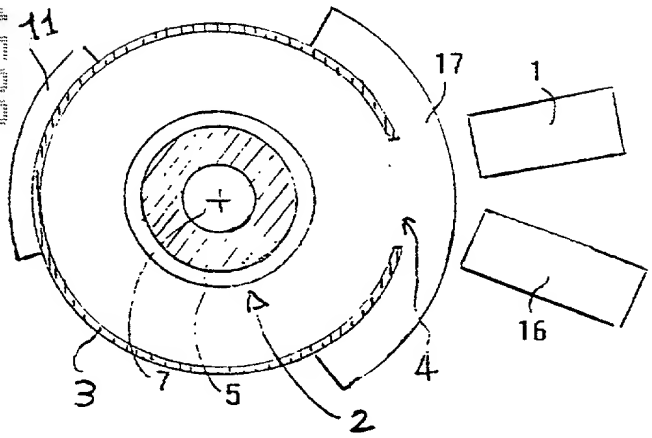

Fig. 3

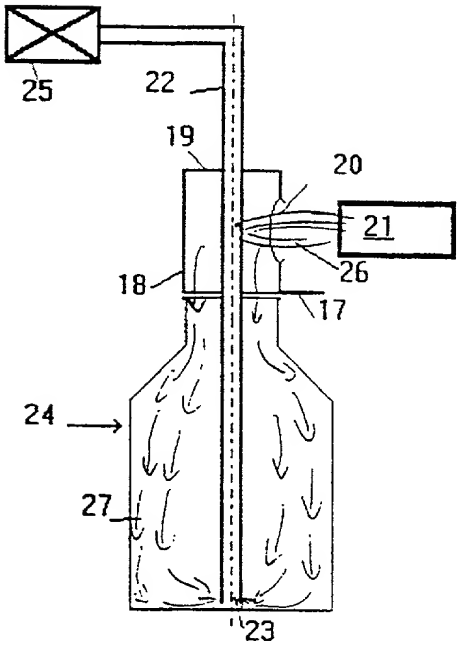

Fig. 4

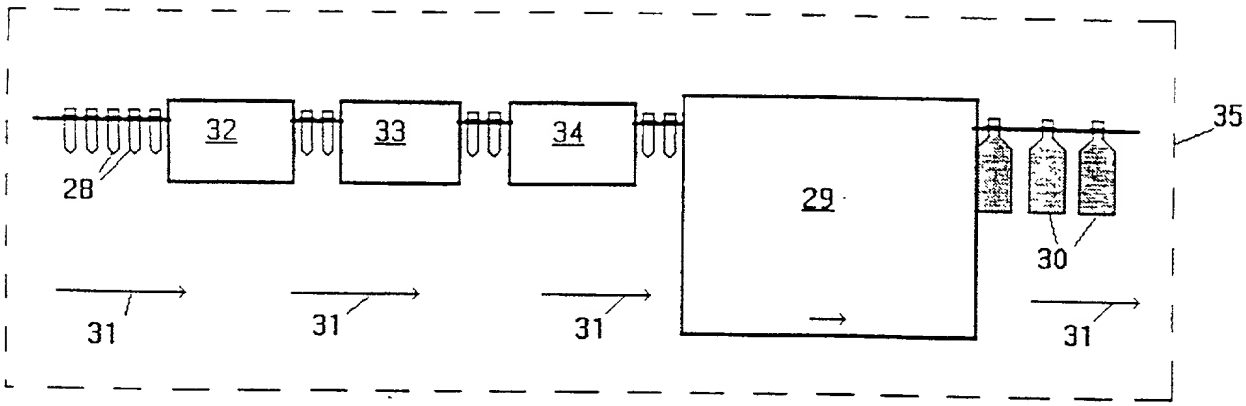

Fig. 5

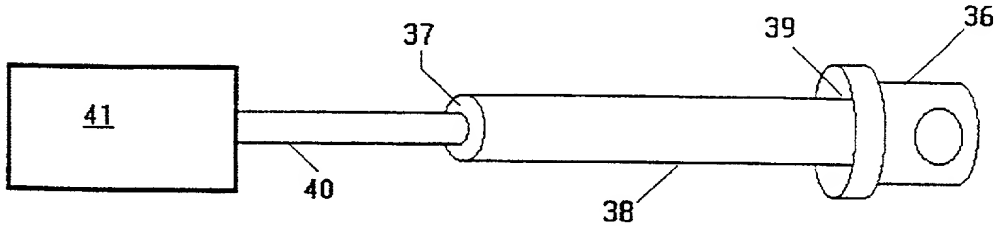

Fig. 6

SOLE/JOINT

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name: that I verily believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter claimed and for which a patent is sought in the application entitled:

METHOD AND DEVICE FOR STERILIZING HOLLOW BODIES

which application is:

☐ the attached application (for original application)

☑ Application No. PCT/FR99/00253 filed February 4, 1999, and amended on

(for declaration not accompanying application)

that I have reviewed and understand the contents of the specification of the above-identified application, including the claims, as amended by any amendment referred to above; that I acknowledge my duty to disclose information of which I am aware which is material to the patentability of this application under 37 C.F.R. 1.56, that I hereby claim priority benefits under Title 35, United States Code §119, §172 or §365 of any provisional application or foreign application(s) for patent or inventor's certificate listed below and have also identified on said list any foreign application for patent or inventor's certificate on this invention having a filing date before that of any foreign application on which priority is claimed:

Application Number	Country	Filing Date	Priority Claimed Yes	Priority Claimed No
98/01937	FRANCE	02/16/98	☑	☐

I hereby claim the benefit of Title 35, United States Code §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in a listed prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge my duty to disclose any information material to the patentability of this application under 37 C.F.R. 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Filing Date	Status

I hereby appoint John H. Mion, Reg. No. 18,879; Thomas J. Macpeak, Reg. No. 19,292; Robert J. Seas, Jr., Reg. No. 21,092; Darryl Mexic, Reg. No. 23,063; Robert V. Sloan, Reg. No. 22,775; Peter D. Olexy, Reg. No. 24,513; J. Frank Osha, Reg. No. 24,625; Waddell A. Biggart, Reg. No. 24,861; Louis Gubinsky, Reg. No. 24,835; Neil B. Siegel, Reg. No. 25,200; David J. Cushing, Reg. No. 28,703; John R. Inge, Reg. No. 26,916; Joseph J. Ruch, Jr., Reg. No. 26,577; Sheldon I. Landsman, Reg. No. 25,430; Richard C. Turner, Reg. No. 29,710; Howard L. Bernstein, Reg. No. 25,665; Alan J. Kasper, Reg. No. 25,426; Kenneth J. Burchfiel, Reg. No. 31,333; Gordon Kit, Reg. No. 30,764; Susan J. Mack, Reg. No. 30,951; Frank L. Bernstein, Reg. No. 31,484; Mark Boland, Reg. No. 32,197; William H. Mandir, Reg. No. 32,156; Brian W. Hannon, Reg. No. 32,778; Abraham J. Rosner, Reg. No. 33,276; Bruce E. Kramer, Reg. No. 33,725; Paul F. Neils, Reg. No. 33,102; Brett S. Sylvester, Reg. No. 32,765; Robert M. Masters, Reg. No. 35,603 and George F. Lehnigk, Reg. No. 36,359, my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and request that all correspondence about the application be addressed to **SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC**, 2100 Pennsylvania Avenue, N.W., Washington, D.C. 20037-3213.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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